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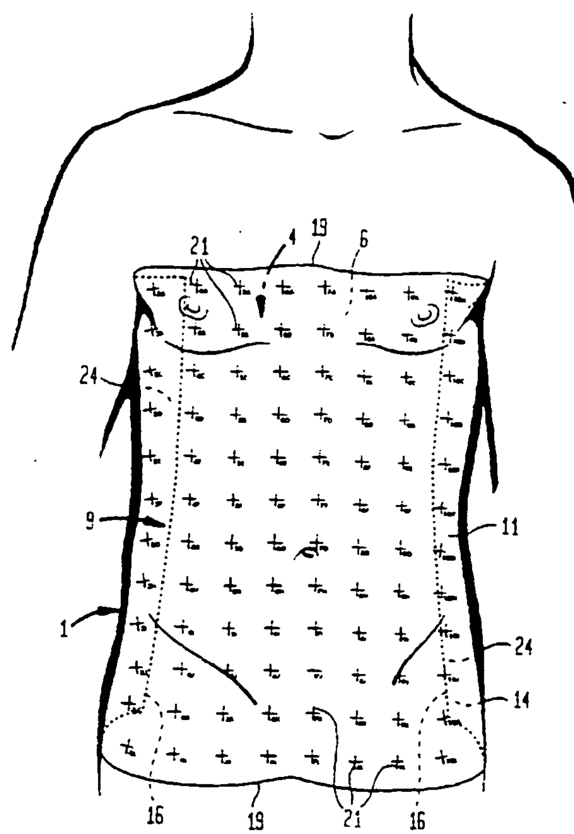

(57) Abstract: The surgical targeting system (1) provides a series of coordinates/lines (21) within a sheet (9) of sterile, flexible material with an adherent surface (11) which is applied to the skin (6) (after suitable surgical application). The sheet (9) is non-porous and may have a topical antiseptic on the side (11) which is applied to the skin (6). A fluoroscope or roentgenographic image (3) of the portion of the body (4) to which the adherent film (9) is applied will show the underlying skeletal and radiopaque elements as well as the overlying surgical grid (21). Once the sheet (9) is applied, the coordinates on the grid lines (21) are clearly visible on the surface of the skin (6) as well as on the fluoroscopic or radiographic image (3) and by knowing the direction of the fluoroscopic or radiographic beam, the operator will be able to thereby correlate a specific locus on the skin (6) with an underlying skeletal element or other underlying radiopaque structure.

WO 01/80738 A1

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SURGICAL TARGETING SYSTEM

Brief Statement of the Invention

The surgical targeting system of the present invention is a device that allows the surgeon to intraoperatively pinpoint a location as well as the surgical corridor for accessing that location within the confines of the human body using fluoroscopy or other radiographic imaging modalities while maintaining and safeguarding a sterile surgical field. If there is a visible laser light beam (parallel to the beam of the X-ray) on the emitter and receiver tube of the C-arm fluoroscope, the device also enables the operator to obtain projections or fluoroscopic views or X-rays identical to one gotten earlier in a procedure during which multiple other intervening views have been taken.

Once a desired target site has been found on the fluoroscopy monitor, it may be transferred directly to the corresponding exterior location on the patient. The point of skin incision as well as the angle of incidence of the surgical corridor (for instrument or implant placement) are given by the locus on the grid and the direction of the radiographic/fluoroscopic beam (which can be altered in three dimensions). By applying the device to the skin of the patient's body and/or body part *e.g.*, limb circumferentially or hemicircumferentially, the operator may take advantage of a parallax effect for more precise targeting and the corridor can be "visualized" or determined by the surgeon in three dimensions. Thus, for example, by utilizing two systems placed on two body surfaces situated on opposite surfaces of the body/body part, a specific locus which simultaneously resides between the imaged surgical targeting systems can be percutaneously accessed via the collinear corridor given by the direction of the fluoroscopic X-ray beam, and the near and far surgical targeting system grid coordinates. The depth of advancement of the surgical instrument or implant is given by a

fluoroscopic/X-ray view (with overlying surgical targeting grid) taken at right angles to the first.

Also, if the depth of the target and the ratio of its distance from the skin of the "near" grid to the "far" grid determined (by an X-ray or fluoroscopic view) then comparison of near and far grids with an intervening target tissue or implant or foreign body and notation of corresponding collinear near and far grid coordinates can be used to mathematically derive other collinear near grid coordinate-target far grid coordinate combinations-without the need for a series of further "empiric" or trial fluoroscopic or X-ray views.

Background of the Invention

It is common practice in the taking of medical X-rays to place a pre-shaped lead marker on a portion of the patient's body to be examined. In common practice, for example, the lead marker "R" or "L" are used to distinguish the right from the left side of the body. Other markers serve to provide a visual reference point in the resultant X-ray film to facilitate interpretation of the X-ray. Once the preferred body structure has been determined on the film, its location can be ascertained relative to this lead marker.

It is also common practice in surgery (for cases in which fluoroscopic X-rays are utilized as a means of guiding the placement of instruments or implants during the procedure) to use a sterile surgical instrument by means holding it over a specific point on the patient's skin (after it has been prepped as a sterile field) while obtaining a fluoroscopic image. This enables the surgeon to plan the skin entry point of a percutaneous procedure. By acquiring the image with the tip of a superimposed surgical instrument held at the same locus on the patient's skin, an assessment of position relative to structures seen on the fluoroscopic image can be ascertained by the surgeon. If the first position selected by the surgeon is off the desired point on the fluoroscopic image, an adjustment is made by moving the instrument to a new locus and a second image is obtained. This procedure is

repeated until the overlying instrument is at the correct spot on the skin corresponding to the appropriate locus on the fluoroscopic image. By moving the C-arm fluoroscope so that the direction of the beam is at 90 degrees to the initial one, an assessment of depth to the target locus can be made. This is the process that is utilized when finding the correct start point on the outer distal femur for interlocking nailing (with the modification of depth assessment where the second view is often obtained to verify screw length) and applies to circumstances where the instrument or implant is to be advanced "end on" the target tissue and parallel to the direction of the fluoroscopic or roentgenographic beam. In instances where this is not the case, *e.g.*, when the start point for an intramedullary nailing on the skin needs to be determined, knowing that this position on the skin must be collinear with the proximal femoral shaft, the assessment of colinearity can be accomplished by applying the surgical targeting grid of the present invention so that it is collinear with the proximal femur on the lateral aspect (this may require C-arm fluoroscopic X-ray check during the act of grid placement, with extension of the placement cephalad as far as the buttock) as well placement of a second grid on the anterior aspect with extension cephalad as far as the buttock at which point it overlaps the first surgical targeting system. By noting which grid row overlies the proximal femoral canal on the anteroposterior projection and also noting which grid row from the second surgical targeting system overlies the proximal femoral canal on the lateral projection, the start point on the skin is given by the intersection of these two rows on the surface of the buttock area. This is of special importance in percutaneous intramedullary nailing procedures, where the selection of an incision point which is not collinear with the proximal femur may cause tenting of a large cuff of soft tissue during the procedure and may necessitate extension of a small incision. Finding this point on the skin might otherwise entail multiple fluoroscopic X-ray views, each of which impart radiation exposure to the patient as well as the surgeon and other operating room personnel. An additional point is that accurate location of this point permits a

small skin incision and this, with healing becomes a small scar which, if later extraction of the device is opted for, facilitates the accomplishment of the procedure, again, as a percutaneous one (with a limited incision whose locus is given by the existing scar).

Another example of the utility of the system of the present invention is provided by the procedure of reamed femoral intramedullary nailing. When the currently commonly utilized process (using an overlying radiopaque object to find a locus on the skin as described above) is used to monitor the passage of a surgical instrument down a surgical corridor, multiple additional fluoroscopic views may be needed. An example of this would be passage of a guidewire down an intramedullary canal for a fracture of the femur. Knowing which direction to point the angled tip of the guide wire entails knowing which direction the fragment on the other side of the fracture is displaced. Additional spot fluoroscopic views of the fracture with an overlying radiopaque object (such as a hemostat clamp, such as for clamping a blood vessel) gives the needed answer and prompts the surgeon to rotate the guidewire so that its tip is toward the intramedullary canal on the displaced fragment before advancing the wire down the fragment's canal. With a surgical targeting device of the present invention in place, obtaining additional fluoroscopic X-rays for this purpose are unnecessary. The added advantageous factor is that the surgeon need not place his hand near the radiation beam with the surgical instrument (this is an occupational hazzard for many surgeons). Additionally, minor directional adjustments in the passage of a radiopaque instrument or implant in the body can be subject to less guesswork because both the coordinates on the fluoroscopic screen and those directly readable on the patient can be correlated. "Guesswork" however may prompt the operator to take more fluoroscopic X-rays or may result in the need for several passes through the patient's tissues with the instrument or implant before the correct corridor is gotten. Having an in place targeting system of the present invention, therefore, may provide the surgeon with a series of constant

reference points throughout the entirety of the procedure. Having these may facilitate the accuracy and speed of the procedure and diminish the potential hazzard to the patient (additional radiation exposure and damage to tissues from inaccurate passage of instruments or implants under fluoroscopic control) as well as to the surgeon and the operating room personnel (radiation exposure).

U.S. Patent 5,702,128 discloses a radiographic marker system and method of making it. The entire disclosure of U.S. Patent 5,702,128 is hereby incorporated by reference herein. U.S. Patent 5,052,035 (referred to herein as the "'035 patent") discloses image location marking devices for radiographs, a method of marking and methods of use. The entire disclosure of U.S. Patent 5,052,035 is hereby incorporated by reference herein.

Instead of a lead marker, the device disclosed in the '035 patent produces multiple parallel lines on an X-ray film bearing a radiographic image of a patient's body to facilitate the location of a part of the body or a retained foreign body or implant within that image. The device comprises a flexible substrate formed of a porous, translucent or transparent material having lines of a radiopaque material disposed thereon. The device is used by applying it over a selected portion of the patient's body to be X-rayed or scanned using computed tomography (CT). The resulting radiographic image of the selected portion of the person's body thus has indicator lines crossing it, which facilitates the demarcation of a desired portion of that image. A marking instrument, *i.e.*, a marking pen, can be applied to the substrate at predetermined locations thereon while the device is on the person to mark the body at the selected location.

The device disclosed in the '035 patent is non-sterile and, therefore, can only be used in a non-sterile environment. Once the corresponding location has been marked on the patient's body, the device disclosed in the '035 patent is removed and discarded. The biopsy is then carried out normally using the mark placed on the skin as a reference point. If the surgeon would like to take another

image with the device disclosed in the '035 patent in place, he would have to compromise the sterile field by replacing the device.

The Ioban® drape is a thin, flexible, adhesive sheet of plastic designed for use during a surgical procedure. The Ioban® drape is 100% impervious to liquid and bacteria, but permeable to oxygen and moisture vapor. Accordingly, a drape that is impervious to liquid strike through or fluid flow through it is an important feature of this device of the present invention. On the other hand, a drape that allows fluid transfer, and thus bacterial transfer, compromises the sterile field. This, in turn, potentially increases the risk of wound infection. For surgical procedures of length, active antimicrobial on the skin in the operative field is a desirable feature. Thus, the inclusion of an antiseptic coating on the drape of the present invention exposed to the skin provides an additional safeguard against infection.

Once a patient's skin has been prepped or prepared for surgery, the sterile Ioban® drape of the present invention is stretched over the area to be incised. The designed function of the Ioban® drape is to provide an added sterile and antiseptic protective barrier within the surgical field placed on the patient's skin and the adjacent operating environment. The Ioban® drape's adhesive properties are often used as a means of securing the sterile drapes or towels to the margins of the surgical field. This feature is an important one when the surgeon is planning a percutaneous procedure with fluoroscopic control, because securing the drapes and towels to the margins of the field in the customary fashion with the use of radiopaque towel clips might otherwise interfere with the ability of the operator to visualize the target or targeted area within the body on the fluoroscopic image.

Summary of the Invention

This invention consists of a thin radiolucent sheet of translucent or transparent material upon which is located a series of radiographically dense numbered and/or lettered lines or otherwise distinguishable markings. One possibility is to dispose a set of lines at regular intervals and a second set of similarly disposed radiographically dense numbered and/or lettered lines are at right angles to the first, so as to form a series of small distinguishable quadrants or intersecting points, *i.e.*, a grid. Many patterns for the design of these patterns are possible, depending on the particular application. These lines as well as their labels are readily seen directly when applied to the patient's body and are also clearly visible when the area to which they are applied is imaged with fluoroscopic x-rays.

Other features of the invention are that the sheet is sterile and the side that is applied to the patient's skin has a uniform distribution of adhesive (although the amount of adhesive is contingent on the specific application). Additionally, the side of the drape applied to the patient's skin also may have a topical antiseptic. The sheet comes with a second layer on the adhesive side, which readily peels off and allows for application of the adherent portion of the targeting grid sheet to the skin of the patient.

Application of the surgical targeting grid to the surface of the body permits a more accurate localization of radiodense structures or bodies within the zone of targeting by fluoroscopic or radiographic imaging. A surgical instrument or implant can be directed to the target tissue or target object by taking advantage of the surgical targeting system in several ways. For example, once the grid marking or coordinate overlying the target on the fluoroscopic image is located on the surface of the body, that becomes the start point for the passage of the instrument/implant to the target, with care to remain co-linear with the fluoroscopic/X-ray incident beam. Additionally, by disposing the surgical targeting sheet around the portion of the body to be imaged in a

hemicircumferential or circumferential manner, two grids (on opposite sides of the body or body part or in different planes from each other *e.g.*, the lateral side and anterior surface of the thorax) can be simultaneously utilized to locate a lesion or a structure. Advantage can thus be taken of the parallax effect of two grids, with one being disposed on the near (to the receiver tube of fluoroscope ((image intensifier)) or developing cassette of the X-ray) body surface and one being disposed on the far or opposite body surface. Determination of depth and relative angle of passage can be ascertained by a grid and corresponding fluoroscopic image or X-ray of the target or passing instrument or implant at right angles to the parallel near and far grids. Overlapping near and far (located on opposite sides of the body or limb) grids can also be utilized in enabling the operator to exactly duplicate a fluoroscopic/X-ray view that was gotten earlier in a procedure. This can occur by making note of overlapping near and far grid coordinates on the view of interest gotten prior. Duplicating this angle of fluoroscopic incident beam can be done by fulfilling this same requirement getting the prior noted grid coordinates to overlap on each other on the image.

Possible methodologies to assure consistent angle of incidence of the fluoroscopic beam can also be facilitated by having a visible laser light beam emanating from an adjustable position on the fluoroscopic emitter tube (X-ray tube) in a direction parallel to the fluoroscopic/X-ray beam. Co-locating the target, the grid marking and the incident visible laser from the emitter tube will allow for more accurate placement of instrument/implant. Once the co-location of the three has occurred (target, grid marking and incident laser light, the operator starts the passage of the instrument/implant at the skin surface at the grid marking which overlies the target on the fluoroscopic view, and maintains the instrument during the course of its passage in line with the incident laser beam. Additional accuracy can be gotten by way of the same technique, but utilizing two surgical targeting grids and having the laser light beam from the receiver

tube (also parallel to the fluoroscopic/X-ray beam) centered at the overlapping far grid coordinate on the opposite side of the body/body part.

Other mechanisms for passage of instruments/ implants to a target point can be done by utilizing the near and far overlapping grid method, and then utilizing a "C" targeting device.

Accordingly, the surgical targeting system of the present invention provides a series of coordinates/ lines within a sheet of sterile, flexible material with an adherent surface which is applied to the skin (after suitable surgical preparation). The sheet is non-porous and may have a topical antiseptic on the side which is applied to the skin. A fluoroscope or roentgenographic image of the portion of the body to which the adherent film is applied will show the underlying skeletal and radiopaque elements as well as the overlying surgical grid. Once the sheet is applied, the coordinates on the grid lines are clearly visible on the surface of the skin as well as on the fluoroscopic or radiographic image and by knowing the direction of the fluoroscopic or radiographic beam, the operator will be able to thereby correlate a specific locus on the skin with an underlying skeletal element or other underlying radiopaque structure. The directional pathway between the two points is given by the direction of the incident radiographic/ fluoroscopic beam. By disposing the surgical targeting system on two opposite sides of the body or body parts, two loci-one on the set near the receiving tube of the fluoroscope (or the developing cassette or "film" of the roentgenograph), and one set of coordinates corresponding to the set on the opposite side of the body or imaged body part, *e.g.*, a limb can be utilized. By noting the targeted zone's relationship to the overlying near and far coordinates, their colinearity can be taken advantage of by the operator for targeting, since both far and near grid coordinates are clearly visible on the surface of the patient's body. A third grid at right angles to the parallel far and near grids can be used to assess depth of advancement of the instrument or probe or biopsy tool to assure the placement of the tip of the device in the target tissue (or implant or

foreign body). It should be pointed out that the operator is not limited to one surgical corridor by this technique. Any number of potential surgical corridors can be located by varying the angle of the incident fluoroscopic or x-ray beam and then noting the overlying far and near grid coordinates. By applying the drape of the surgical targeting system to the part of the body in a circumferential or nearly circumferential manner, and utilizing a radiolucent operating room table, and a C-arm fluoroscope, the aforementioned targeting techniques can be utilized at surgery. Multiple targeting or percutaneous procedures can be performed at the same sitting with the application of a single drape.

These and other features and advantages of the invention will be more fully understood from the following description of specific embodiments of the invention taken together with the accompanying drawings.

Brief Description of the Drawings

Fig. 1 is an anterior view of an embodiment of the surgical targeting system of the present invention applied to the torso of a body;

Fig. 2 is a view of a radiographic image of the torso of **Fig. 1** with the surgical targeting grid and skeletal elements visible;

Figs. 3, 4 and **5** are views in the plane of **Fig. 1** showing alternative rectangular coordinate configurations of the radiopaque elements of the surgical targeting system;

Fig. 6 is an anterior view of the surgical targeting system of **Fig. 1** applied to the torso;

Fig. 7 is a lateral view of the surgical targeting system of **Fig. 6** with the patient lying supine on the operating table;

Fig. 8 is an anterior view of the surgical targeting system of **Fig. 6** with the patient lying supine on the operating table and viewed from above (anterior aspect);

Fig. 9 is a superior view of the surgical targeting system of **Fig. 6** with the patient lying on the operating room table from above with the emitter and receiving tubes of a C-arm fluoroscope depicted in position to obtain a lateral view of the targeted area;

Fig. 10 is a view of a C-arm fluoroscopic image obtained from the apparatus depicted in **Fig. 9**;

Fig. 11 is a superior view of the surgical targeting system of **Fig. 6** with the patient lying on the operating room table from above with the emitter and receiving tubes of a C-arm fluoroscope depicted in position to obtain an anterior to posterior view of the targeted area;

Fig. 12 is a view of a C-arm fluoroscopic image obtained from the apparatus depicted in **Fig. 11**;

Fig. 13 is an anterior view of a lower trunk with the surgical targeting system of **Fig. 1** applied to the anterior aspect as well as both sides, the emitter and receiving tubes of a C-arm fluoroscope being depicted in position for a lateral view of the targeted area;

Fig. 14 is a lateral view of the surgical targeting system applied to the lower trunk of **Fig. 13** from the lateral (side) aspect, the emitter and receiving tubes of a C-arm fluoroscope being depicted in position for an anteroposterior view of the targeted area;

Fig. 15 is a view of the fluoroscopic image of the sacral elements and overlapping near and far surgical targeting grids obtained from the apparatus depicted in **Fig. 13**;

Fig. 16 is a view of the fluoroscopic view of the skeletal elements and overlying surgical targeting grid obtained from the apparatus depicted in **Fig. 14**, the position of an iliosacral screw used to address an unstable sacroiliac joint also being shown;

Fig. 17 is a medial (inner) aspect view of the surgical targeting system of **Fig. 1** applied from the mid-thigh to mid-leg levels of a lower limb;

Fig. 18 is an anterior (front) aspect view of the surgical targeting system of **Fig. 17** applied from the mid-thigh to mid-leg levels of the lower limb;

Fig. 19 is a lateral (outer) aspect view of the surgical targeting system of **Fig. 17** applied from the mid-thigh to mid-leg levels of the lower limb;

Fig. 20 is a posterior (rear) aspect view of the surgical targeting system of **Fig. 17** applied from the mid-thigh to mid-leg levels of the lower limb, the surgical targeting system not being applied to the central axial portion of this aspect of the limb;

Fig. 21 is a view of a radiographic image of the skeletal elements and overlapping surgical targeting system of **Fig. 17**;

Fig. 22 is a view of a radiographic image of the skeletal elements and overlapping surgical targeting system of **Fig. 18**;

Fig. 23 is a view of a radiographic image of the skeletal elements and overlapping surgical targeting system of **Fig. 19**;

Fig. 24 is a view of a radiographic image of the skeletal elements and overlapping surgical targeting system of **Fig. 20**;

Fig. 25 is a C-arm fluoroscopic view of the distal femur from the lateral (or medial) aspect with the overlapping surgical targeting system of **Fig. 23**, targeting of the holes in the distal portion of a femoral intramedullary nail being facilitated by the near and far grid coordinates in the target nail hole such that with the grid properly positioned, these coordinates are directly read on the skin surface;

Fig. 26 is a perspective view of an alternative embodiment of the surgical targeting system of **Fig. 1** applied to a digit (finger depicted), the rolled closed tube being capable of being unrolled from the tip of the digit;

Fig. 27 is a perspective view of the surgical targeting system of **Fig. 26**, the rolled closed tube being unrolled further toward the base of the digit;

Fig. 28 is a view of a radiographic image of the digit and overlying surgical targeting system of **Fig. 27** illustrating the skeletal elements of the digit;

Fig. 29 is a perspective view of an alternative embodiment of the surgical targeting system of **Fig. 26**;

Fig. 30 is a perspective view of the surgical targeting system of **Fig. 29** illustrating the rolled closed tube unrolled further toward the base of the digit;

Fig. 31 is a perspective view of an alternative embodiment of the surgical targeting system of **Fig. 1** for application to a human breast, the surgical targeting system including a cone-shaped drape with a cutout having an aperture in the center corresponding to the nipple of the breast;

Fig. 32 is an anterior view of the surgical targeting system of **Fig. 31** showing the surgical grid as a polar coordinate system;

Fig. 33 is a superior view of a patient to whom the surgical targeting system of **Fig. 31** is applied, the patient undergoing mammographic imaging where the emitter tube is medial and the receiving tube is lateral;

Fig. 34 is a view of the fluoroscopic mammographic image obtained from the apparatus depicted in **Fig. 33** showing a lesion located cephalad, in line with the specific grid markings illustrated;

Fig. 35 is a lateral view of a patient to whom the surgical targeting system of **Fig. 31** is applied, the patient undergoing mammographic imaging where the emitter tube is cephalad (above) and the receiver tube is caudad (below); and

Fig. 36 is a view of the fluoroscopic mammographic image obtained from the apparatus depicted in **Fig. 35** showing a lesion located laterally, in line with the specific grid markings illustrated.

Corresponding reference characters indicate corresponding parts throughout the several views of the drawings.

Detailed Description of the Invention

The surgical targeting system of the present invention combines the advantages of both a marking device for radiograph and a plastic adhesive wound drape such as the Ioban® drape. The device is composed of a thin, sterile flexible, transparent or translucent sheet which has varying amounts of uniformly distributed adhesive and topical antiseptic such as iodophor on the side which is to be applied to the patient's skin. To facilitate packaging and application to the patient, a removable and disposable layer on the adherent side (which is pealed off when applied) may be incorporated.

Additionally, a series of easily distinguishable radiopaque lines are incorporated either on or within the layers of the drape. One method of distinguishing the radiopaque lines is their being disposed in a pattern and labeled with radiopaque material. The pattern of the radiopaque elements and the labels/coordinates are easily visible on the drape as well as on a radiographic/fluoroscopic image of the drape. The radiopaque medium forms a distinctive pattern of lines on the drape, which allows for easy localization of the pathology or the targeting point within the radiographic image. The radiopaque medium may be, but is not limited to, fine steel wire (having a diameter of 0.003 inches) or a slurry of some radiopaque material such as barium or calcium sulfate.

The material of the lines is radiopaque while the surgical drape material is radiolucent, which means only the lines of the drape and their corresponding coordinate markings are visible when a roentgenographic/fluoroscopic image of the drape is obtained. The drape material is transparent or translucent enough to allow the operator to directly read and distinguish the lines from one another when the drape is applied to the skin of a patient. One method of facilitating this distinction is to make the lines with discrete shapes, such as a zigzag, sine wave, square wave, or loops.

Another method of distinction is straight lines with labels at each intersection that more readily facilitate the identification of the intersection of two of the lines. One possibility is to label the lines numerically along one axis and alphabetically along the other. By doing so, the surgeon is able to visually detect on the fluoroscopy monitor a set of intersecting labeled lines and may thereby distinguish each point of their intersection, such as **C4**, **B2**, **T9**, etc. With this system, each intersection (and each quadrant delineated by four such intersections disposed at the corners of each quadrant) is uniquely identifiable. The proportion of the label to the size of the square is such that it is easily read from the monitor as well as directly and does not interfere with the image within the square. When the squares are small in size, this may necessitate labeling every other row or every few rows or only along the margins of the lines.

A surgical targeting system of the present invention, is designated generally by the reference numeral **1** in **Fig. 1**. The surgical targeting system **1** is used for adding an indicia image **2** to a radiographic image of a body **3** resulting from passage of image radiation through the body **4**, as illustrated in **Fig. 2**.

The surgical targeting system **1** comprises an antimicrobial drape **9** having an inner surface **11** of sufficient flexibility to conform to at least a portion of the outer surface **6** of the body **4**. The drape **9** comprises a plastic impregnated with iodophor. A preferred embodiment of the drape **9** is disclosed in the publication "3M® Ioban® 2 Antimicrobial Incise Drapes: Clinical Use Information" by 3M Health Care, the entire disclosure of which is hereby incorporated by reference herein. The inner surface **11** of the drape may be coated with an antiseptic. The drape **9** has an outer surface **14**, and longitudinal and lateral edges **16**, **19**. The drape **9** is puncturable to provide access to the outer surface **6** of the body **4**. The drape **9** is transparent to the imaging radiation.

The targeting system **1** further comprises an indicia **21** affixed to a portion of the drape **9**. The indicia **21** are opaque to the imaging radiation resulting in the indicia image **2** corresponding to the indicia **21**.

The targeting system further comprises a means for fixing the indicia **21** relative to the outer surface of the body **4** such that the indicia provide a reference on the body **4** for correlating portions of the body **4** to the radiographic body image **3**. The fixing means may comprise adhesive **24** continuously applied to the entire inner surface **11** of the drape **9**.

An emitter, such as an X-ray tube, and a receiver, such as an image intensifier, directed at one another in perpendicular relation to the plane of **Fig. 1**, may be employed to produce the image illustrated in **Fig. 2**. **Fig. 2** includes indicia images **2** (corresponding to the indicia **21**), a body image **3** (corresponding to the body **4**), and a skeleton image **26**.

The indicia **21** may be constituted by various coordinate or grid systems such as are illustrated in **Figs. 3, 4** and **5**. For a rectangular coordinate system, examples of which are shown in **Figs. 3, 4** and **5**, the radiopaque medium forms two sets of thin lines. Each set of lines is parallel and equidistant to one another. One set of the lines is oriented 90° to the other to form a grid. The result is a pattern of radiopaque squares of equal size. These squares may range in size from 1 millimeter to a few centimeters across depending on the grid pattern needed for a specific application. The material comprising the lines must be such that the Ioban® drape material retains its flexibility so that it stretches over the complex curves of the human body. For instance, if the lines are composed of steel wires, each wire may be broken at every location where it crosses another wire as shown in **Fig. 4**. An alternative pattern which would fulfill this requirement would be the pattern shown in **Fig. 5**. In this manner, the segments of wire are free to move relative to each other, and the flexibility of the drape is not significantly compromised.

Figs. 6, 7 and **8** illustrate an embodiment of the surgical targeting system **29** in which the surgical targeting system **1** is applied to anterior, lateral and posterior portions of the outer surface **34** of the chest or torso **31** of a body. The surgical targeting system **29** includes a drape **36** (corresponding to the drape **9**),

outer and inner surfaces **39, 41** (corresponding to the outer and inner surfaces **11, 14**), and longitudinal and lateral edges **44, 46** (corresponding to the longitudinal and lateral edges **16, 19**). The surgical targeting system **29** also includes indicia **56** (corresponding to the indicia **21**) and adhesive **59** (corresponding to the adhesive **24**). The drape **36**, as applied to the torso **31**, has anterior, lateral and posterior portions **49, 51, 54**, as illustrated in **Figs. 6, 7 and 8.**

An emitter **61**, such as an X-ray tube, and a receiver **64**, such as an image intensifier, arranged as shown in **Figs. 9** and **11**, may be employed to produce the images illustrated in **Figs. 10** and **12**, respectively. **Figs. 10** and **12** include indicia images **65** (corresponding to the indicia **56**), a lesion image **66**, rib images **69** and a sternum image **71.**

The anatomical terms "superior" **a** and "inferior" **b**, with respect to the human body, refer to locations nearer to the head and to the feet of the body, respectively, relative to other locations. The anatomical terms "anterior" **c** and "posterior" **d**, with respect to the human body, refer to locations nearer to the front of and to the back of the body, respectively, relative to other locations. The term "lateral" refers to a location to the right or left sides of the body, relative to other locations. Alternatively, "lateral" refers to one or other side of the mid-line, with respect to the major axis of the body, or to a device lying in the major axis of the body. The term "medial" **m** refers to nearer to the mid-line. The left- and right-hand sides of the body are designated by the reference characters **l** and **r**, respectively.

Figs. 13 and 14 illustrate an embodiment of the surgical targeting system 74 in which the surgical targeting system **1** is applied to anterior and lateral portions of the outer surface **79** of the lower trunk **76** of a body. The surgical targeting system **74** includes a drape **81** (corresponding to the drape **9**), outer and inner surfaces **84**, **86** (corresponding to the outer and inner surfaces **11, 14**), and longitudinal and lateral edges **89, 91** (corresponding to the longitudinal and lateral edges **16, 19**). The surgical targeting system **74** also includes indicia **99**

(corresponding to the indicia **21**) and adhesive **101** (corresponding to the adhesive **24**). The drape **81**, as applied to the lower trunk **76**, has anterior and lateral portions **94**, **96**, as illustrated in **Figs. 13 and 14.**

An emitter **104**, such as an X-ray tube, and a receiver **106**, such as an image intensifier, arranged as shown in **Figs. 13 and 14**, may be employed to produce the images illustrated in **Figs. 15 and 16**, respectively. **Figs. 15 and 16** include indicia images **108** (corresponding to the indicia **99**), an S1 vertebrae image **109**, an S2 vertebrae image **111**, an S3 vertebrae image **114**, an L4 vertebrae image **116**, an L5 vertebrae image **119**, a sacrum image **121**, and a nail image **122**.

Figs. 17, 18, 19 and **20** illustrate an embodiment of the surgical targeting system **124** in which the surgical targeting system **1** is applied to the outer surface **129** of the lower limb **126** of a body. The surgical targeting system **124** includes a drape **131** (corresponding to the drape **9**), outer and inner surfaces **134**, **136** (corresponding to the outer and inner surfaces **11**, **14**), and longitudinal and lateral edges **139**, **141** (corresponding to the longitudinal and lateral edges **16**, **19**). The surgical targeting system **124** also includes indicia **144** (corresponding to the indicia **21**) and adhesive **146** (corresponding to the adhesive **24**).

An emitter, such as an X-ray tube, and a receiver, such as an image intensifier, directed at one another in perpendicular relation to the planes of **Figs. 17, 18, 19,** and **20**, may be employed to produce the images illustrated in **Figs. 21, 22, 23** and **24**, respectively. **Figs. 21, 22, 23** and **24** include indicia images **147** (corresponding to the indicia **144**), a lower limb image **148** (corresponding to the lower limb **126**), and bone images **149**.

Fig. 25 is a view corresponding to **Fig. 23**. Accordingly, images in **Fig. 10** corresponding to images in **Figs. 23** have the same reference numeral with the addition of the suffix **a**. **Fig. 25** contains a nail image **151** of a femoral intramedullary nail having hole images **154**. The indicia images **144a** labeled "**3G**" and "**10G**" are shown positioned such that an axis intersecting these indicia

images extends through one of the hole images **154** to facilitate location of the one hole in the intramedullary nail.

Figs. 26 and **27** illustrate an embodiment of the surgical targeting system **156** for application to the outer surface **161** of an elongate portion of a body such as finger **159**. The surgical targeting system **156** includes a drape **164** of similar material as the drape **9**. The drape **164** has an inner surface **169** which, like the inner surface **14** of the drape **9**, may be coated with an antiseptic. The surgical targeting system **156** has indicia **179** similar to the indicia **21**.

The drape **164** has a cylindrical portion **174**, one end of which is closed by a connected hemispherical end portion **176**. The opposite end of the cylindrical portion **174** is defined by a rim **171**. Prior to application to the finger **159**, the drape **164** is rolled onto itself as shown in **Fig. 26**. The drape **164** is then applied to the end of the finger **159**, as shown in **Fig. 26**, and unrolled to cover the finger as shown in **Fig. 27**.

The surgical targeting system **156** includes means for fixing the indicia **179** relative to the outer surface **161** of the finger **159**, similar to the fixing means of the surgical targeting system **1**. Accordingly, adhesive **181** may be continuously applied to the entire inner surface **169** of the drape **164**. Alternatively, or in addition to the adhesive **181**, the drape **164** may be fixed to the outer surface **161** of the finger **159** by forming the drape of expandable material and sizing it to have an internal volume which is less than the volume of the finger such that the drape is shrink-fitted onto the finger.

An emitter, such as an X-ray tube, and a receiver, such as an image intensifier, directed in side elevation toward the surgical targeting system **156** as applied to the finger **159** in **Fig. 27** may be employed to produce the image illustrated in **Fig. 28**. **Fig. 28** includes indicia images **182** (corresponding to the indicia **179**), a finger image **183** (corresponding to the finger **159**), bone images **184**, and a fragment image **186**, such as may result from insertion of a foreign body into the finger.

Figs. 29 and **30** illustrate a surgical targeting system **156a** which is an alternative embodiment of the surgical targeting system depicted in **Figs. 26** and **27.** Accordingly, structures in **Figs. 29** and **30** corresponding to structures in **Figs. 26** and **27** have the same reference numeral with the addition of the suffix a. The indicia **179a** of the surgical targeting system **156a** have the shape of "+" in contrast to the indicia **179** which are continuous.

Figs. 31 and **32** illustrate an embodiment of the surgical targeting system **189** for application to the outer surface **194** of a right breast **191** of a body. The surgical targeting system **189** includes a right drape **196** of similar material as the drape **9.** The right drape **196** has an inner surface **201** which, like the inner surface **14** of the drape **9**, may be coated with an antiseptic. The right drape **196** also has an outer surface **199.**

The right drape **196** is conical and has a radial cutout **206.** The cutout **206** has a base **209** which coincides with a peripheral edge **204** of the drape, and a central aperture **211.**

The surgical targeting system **189** has indicia **214** similar to the indicia **21.** The indicia **214** are preferably a system of polar coordinates having a center coinciding with the apex of the right drape **196**, as shown in **Fig. 32.** The indicia **214** of the polar coordinate system shown of **Fig. 32** may include a radiopaque medium forming two sets of thin lines. The first set of lines radiates from a common center. The second set of lines forms concentric circles whose center is coincident with the intersection of the radial lines. The spacing between the radial lines and concentric circles varies from drape to drape depending on the specific application of the drape as well as the size of the tissue to be targeted. Depending on the material chosen to make the lines, the lines may also have to be broken at the intersections, as described herein above for the rectangular coordinate system, to allow for optimal flexibility of the system. Alternatively, if added stiffness is desirable and a specific tissue is hypermobile and therefore less amenable to targeting, a "closed" wire system with thicker and stiffer wires may

be preferred. Each line or intersection is also labeled in a manner analogous to the rectangular coordinate system. A common perceived use for a polar system is with radiographic images produced for a mammographic examination and biopsy.

The surgical targeting system **189** includes means for fixing the indicia **214** relative to the outer surface **194** of the right breast **191**, similar to the fixing means of the surgical targeting system **1**. Accordingly, an adhesive **216** is continuously applied to the entire inner surface **201** of the right drape **196.**

Fig. 31 also illustrates a surgical targeting system **189a** which is an alternative embodiment of the surgical targeting system **189.** Accordingly, the structures of the surgical targeting system **189a** corresponding to structures of the surgical targeting system **189** have the same reference numeral with the addition of the suffix **a**. The surgical targeting system **189a** is for application to the outer surface **194a** of a left breast **191a** of the body.

An emitter **219**, such as an X-ray tube, and a receiver **221**, such as an image intensifier, arranged as shown in **Figs. 33** and **35**, may be employed to produce the images illustrated in **Figs. 34** and **36**, respectively. **Figs. 34 and 36** include an indicia image **222** (corresponding to the indicia **214**), a right breast image **223** (corresponding to the right breast **191**), and a lesion image **224.**

Operation

As an example, a tumor in the mediastinum (the central portion of the chest cavity) may be localized and biopsied/resected (Depicted in the series of **Figs. 6, 7, 8, 9, 10, 11** and **12**). Once the area of the body has been prepped and draped, the sterile pack of the grid system is opened and the grid system is removed. Using aseptic technique, the surgeon peels back the protective sheet of the grid system, exposing the adhesive backed sheet. This can then be applied to the area (now dry) for targeting as well as to secure the neighboring sterile towels and sheets. It is applied, adhesive side down, and pressed firmly in place. **Fig. 6**

shows a patient lying on a radiolucent operating room table with the surgical targeting grid being applied to the sides and anterior aspect of the chest wall, covering the area where the lesion is known to be. **Fig. 7** shows the view of the upper torso of this patient from the side view with the emitter and receiver tubes of the C-arm fluoroscope also depicted in position for an anteroposterior view of the targeted area. **Fig. 8** shows the view of the upper torso of this same patient from the anterior (front) aspect with the surgical targeting system in place. The emitter and receiver tubes of the C-arm are depicted in position for a lateral view of the targeted area. **Fig. 9** shows the same patient from the cephalad aspect with the emitter and receiver tubes in position for the lateral X-ray/ fluoroscopic image which is depicted in **Fig. 10.** **Fig. 11** shows the same patient from the cephalad aspect with the emitter and receiver tubes in position for the anteroposterior X-ray/fluoroscopic image which is shown in **Fig. 12.**

Another example is as an aid in the accomplishment of accurate placement of an iliosacral screw for fixation of an unstable sacroiliac joint following trauma. **Fig. 13** shows an oblique view of a patient lying on a radiolucent operating room table after suitable prepping and draping of the skin to create a sterile surgical field with the surgical targeting grid applied to the anterior and lateral aspects of the lower trunk (pelvic area). **Fig. 14** shows this same patient from the lateral (side) view and emitter/receiving tubes as they would be positioned for an anteroposterior radiographic/fluoroscopic view. **Fig. 15** is a view of the skeletal elements and overlapping near and far surgical targeting grids. Targeting in this instance can proceed from the near hatch mark which is superimposed on the center of the first sacral vertebral body to its nearly collocated counterpart on the far grid (See **Fig. 15**). **Fig. 16** shows the skeletal elements on the anterior view. The depth as well as the angle of incidence of the pin or screw can be ascertained on this view. Subtle alterations in the angle of inclination of this guidewire are critical and it is safest (least likely to injure a nerve) if it is directed slightly cephalad and anterior. Knowing this, the operator may choose to set the collinear

points by adjusting the angle of the incident beam of the fluoroscope just off the lateral, with the near grid point slightly posterior and caudad, the far grid point slightly anterior and cephalad. Simply reading the far and near coordinates overlapping the center of the first sacral body will then give the coordinates on the surface of the body which can then be used to aid targeting.

Targeting these points by way of instruments may be facilitated in several ways, including laser light beams from the emitting and receiving tubes on the C-arm fluoroscope directed parallel to the beam and targeted then at the specific target (near and far respectively) coordinates on the patient. Directionality of the pin or instrument or implant by keeping it exactly within beam of light would aid accurate placement. Alternatively, use may be made of a "C" guide (an instrument that directs the passage of a pin or drill from one point to emerge at a precise second point given by the instrument) where one point of the "C" is on the near target coordinate and the other point of the "C" on the far coordinate.

The surgical targeting grid may also be utilized on the limb to facilitate percutaneous targeting. **Figs. 17, 18, 19** and **20** show the surgical targeting grid applied around three quarters of the circumference of the lower thigh, knee, and upper leg with only the posterior portion of the leg not covered) **Figs. 21, 22, 23** and **24** show the corresponding skeletal elements and overlying surgical grids. Note that on the medial (**Fig. 21**) and lateral (**Fig. 23**) views, there are two grids seen, one near and the other on the far side. With a locking intramedullary nail in place within the femoral intramedullary canal, interlocking the nail (drilling a hole across the femur and through the hole in the nail, followed by the placement of a screw) can be facilitated by precise targeting utilizing the near and far hatch marks at the center of the target-in this case the circle which represents the hole in the intramedullary nail. Targeting the coordinates can be done by using the surface coordinates as described for the iliosacral screw fixation.

Another example is provided by locating a retained foreign body in a finger. **Figs. 26** and **27** show the adaptation of the surgical targeting grid for placement on a digit, with **Fig. 26** showing the system partially and **Fig. 27** showing the system fully unfurled. **Fig. 28** shows the skeletal elements on a lateral roentgenographic/fluoroscopic view with a foreign body. By obtaining an X-ray or C-arm view at right angles to this one, *i.e.,* in the anteroposterior view, the foreign body can be precisely located and extracted with an incision centered at the appropriate location given by the surface coordinates. **Figs. 29** and **30** show an alternative construct of the surgical targeting grid for this application being applied to the digit.

Another example of the surgical targeting system would be for mammographic biopsy. For this application, the adaptation of the surgical grid system is shown in **Fig. 32** where a polar coordinate system is used, *i.e.,* a series of concentric lines at regular intervals are intersected by a series of lines perpendicular to them and converging on the center. The system is cone shaped, to conform to the shape of the breast with a slit and an open center to accommodate different sizes. **Fig. 33** shows the patient from the cranial (top) view with the emitting and receiving tubes inside (medial) and outside (lateral) the breast which is to be imaged after the skin has been prepped appropriately and a surgical field created with appropriate draping, and the surgical targeting system applied. **Fig. 34** shows a roentgenographic/fluoroscopic view of the breast with the overlapping surgical targeting system in place and a lesion visible. **Fig. 35** shows a side (from lateral) view of this same patient's breast with the emitter/receiving tubes cephalad (up or toward the head) and caudad (down or toward the feet) and **Fig. 36** shows the corresponding roentgenographic/ fluoroscopic view with the lesion and overlapping surgical grid. By advancing the biopsy needle/trocar from the appropriate coordinates on the surface of the

breast (**Fig. 34**) to the depth as designated on the view at right angles to it (**Fig. 36**), a more precise localization with fewer "passes" and less irradiation exposure of patient and operator can be achieved.

Another example somewhat analogous to the former is provided by the process that is utilized when finding the correct start point on the outer distal femur for interlocking nailing (with the modification of depth assessment-where the second view is often obtained to verify screw length) and applies to circumstances where the instrument or implant is to be advanced "end on" the target tissue and parallel to the direction of the fluoroscopic or roentgenographic beam. In instances where this is not the case, *e.g.,* when the start point for an intramedullary nailing on the skin needs to be determined, knowing that this position on the skin must be collinear with the proximal femoral shaft, the assessment of colinearity can be accomplished by applying the surgical targeting grid so that it is collinear with the proximal femur on the lateral aspect (this may require C-arm fluoroscopic X-ray check during the act of grid placement, with extension of the placement cephalad as far as the buttock) as well placement of a second grid on the anterior aspect with extension cephalad as far as the buttock-at which point it overlaps the first surgical targeting system. By noting which grid row overlies the proximal femoral canal on the anteroposterior projection and also noting which grid row from the second surgical targeting system overlies the proximal femoral canal on the lateral projection, the start point on the skin is given by the intersection of these two rows on the surface of the buttock area. This is of special importance in percutaneous intramedullary nailing procedures, where the selection of an incision point which is not collinear with the proximal femur may cause tenting a large cuff of soft tissue during the procedure and may necessitate extension of a small incision. Finding this point on the skin might otherwise entail multiple fluoroscopic X-ray views, each of which impart radiation exposure to the patient as well as the surgeon and other operating room personnel. An additional point is that accurate location of this point permits a

small skin incision and this, with healing becomes a small scar which, if later extraction of the device is opted for, facilitates the accomplishment of the procedure, again, as a percutaneous one (with a limited incision whose locus is given by the existing scar).

Another example of the utility of the system is provided by the procedure of reamed femoral intramedullary nailing. When the currently commonly utilized process (using an overlying radiopaque object to find a locus on the skin as described in the section titled "Background of the Invention") is used to monitor the passage of a surgical instrument down a surgical corridor, multiple additional fluoroscopic views may be needed. An example of this would be passage of a guidewire down an intramedullary canal for a fracture of the femur. Knowing which direction to point the angled tip of the guidewire entails knowing which direction the fragment on the other side of the fracture is displaced. Additional spot fluoroscopic views of the fracture with an overlying radiopaque object (such as a hemostat) gives the needed answer and prompts the surgeon to rotate the guidewire so that its tip is toward the intramedullary canal on the displaced fragment before advancing the wire down the fragment's canal. With a surgical targeting device in place, obtaining additional fluoroscopic X-rays for this purpose are unnecessary. The added advantageous factor is that the surgeon need not place his hand near the radiation beam with the surgical instrument which is an occupational hazzard for many surgeons. Additionally, minor directional adjustments in the passage of a radiopaque instrument or implant in the body can be subject to less guesswork because both the coordinates on the fluoroscopic screen and those directly readable on the patient can be correlated. "Guesswork" however may prompt the operator to take more fluoroscopic X-rays or may result in the need for several passes through the patient's tissues with the instrument or implant before the correct corridor is secured. Having an in place targeting system, therefore, may provide the surgeon with a series of constant reference points throughout the entirety of the procedure. Having these will facilitate the

accuracy and speed of the procedure and diminish the potential hazzard to the patient (additional radiation exposure and damage to tissues from inaccurate passage of instruments or implants under fluoroscopic control) as well as to the surgeon and the operating room personnel (radiation exposure - both generally and locally to the surgeon's hand).

Procedures which may utilize the surgical targeting system of the present invention include:

Percutaneous and limited skin incision surgical procedures that are reliant, either totally or partially on guidance from fluoroscopic or conventional X-ray guidance;

Bone fixation;

Biopsy needle/trocar placement;

Bone graft trocar placement;

Bone graft substitute trocar placement;

Localization of gantries for radiation therapy, and placement of radioactive sources for this purpose;

As an aid to the precise direction of electromagnetic radiation, sonic waves directed either singly at an individual target or from multiple projections at a single target;

Locating a foreign object or foreign objects;

Extracting or manipulating these foreign objects percutaneously;

Localization of tracts (e.g, sinus tract infection);

Positioning of ultrasonic or magnetic field stimulation in relation to bone/soft tissue fixation;

Wire and pin placements for cannulated screw fixation and accurate bone anchoring;

Manipulation/removal/repositioning of existing implants;

As an aid to the accomplishment of percutaneous procedures;

As a means of cross checking computer guided or computer assisted surgery Intracranial targeting;

As an aid in biopsying/staging gastrointestinal/ urinary tract tumors (in combination with endoscopic findings-the surgical targeting grid can be used to locate the tip of the endoscope, and thereupon direct the tip of a laparoscope to visualize the outside wall of the viscus for the purpose of staging/biopsy);

As an aid in directing the placement of a mediastinal scope;

As an aid in determining the position of a bronchoscope; and

Placement of other implants or reservoirs.

Alternative embodiments of the invention are possible, in addition to integrating this grid system into a sterile drape. For example, other methods of surgical targeting may be employed by combining a sterile radiopaque grid with a removable glove or sock or a condom for the extremity, finger or other appendage. Such a device is stretchable with enough friction to minimize any shearing between it and the skin and may not require adhesive backing or perhaps only minimal adhesive backing. This device would allow for surgical targeting of the upper and lower extremities. Another embodiment would be that applicable to the breast, *i.e.,* a polar coordinate grid system on a conically shaped sterile plastic adhesive drape with the central portion for the nipple cut out and a slit to permit size adjustment.

By disposing the system around the lower trunk, starting from one lateral side, across the anterior aspect and over the opposite lateral side, the use of parallax by superimposing grids or grids disposed at right angles to each other can be used to find the relation of a locus to the surface coordinates as well as in directing the angle of entry and depth of penetration of the surgical instrument or implant by the operator.

In summary, the surgical targeting system of the present invention includes a surgical adhesive drape (which is form-fit to a specific body part such as a digit, with no possibility for shearing between the skin and the overlying grid) which is transparent or translucent and radiolucent excepting the indicia of the surgical targeting system which are radiopaque and clearly visible both directly and on a radiographic/ fluoroscopic image. Additionally, the drape is impervious to moisture and bacteria and has an option for inclusion of an uniformly distributed topical antiseptic on the surface of the drape which is applied to the body. The surgical targeting system includes one or several patterns of radiopaque lines disposed at right angles to each other and each with distinguishing radiopaque labels. Both the lines and the labels are easily readable both on fluoroscopic views as well as directly once the targeting systems have been applied to the surface of the body.

Simultaneous application of the drape (or separate drapes) to "near" and "far" body surfaces enables the surgeon to take advantage of parallax and utilize both surgical grids for precise direction of a surgical tool or implant such as a needle, drill, pin, rod, biopsy tool or trocar. Similarly, by locating two grids over the body area of interest at right angles to each other, one grid can be used to isolate a starting point and the second grid can be utilized with fluoroscopic views also at right angles to the overlying second grid to control the depth and angle of inclination of the inserted instrument or implant. This feature of parallax can also be utilized in the instance of overlapping (near and far) grids, disposed on opposite sides of the body or body part by assuring co-linearity of the target with far and near grid points. Subtle adjustments in the angle of the radiographic/fluoroscopic beam result in changes in the collinear near and far coordinates.

Once the desired coordinates for passage of the instrument or implant are known, several strategies incorporating the grid coordinates can then be used to assist targeting. One strategy for the accomplishment of this would entail a

visible light beam projection from the middle of the C-arm fluoroscope from both the emitting and receiving elements, directed by the operator to the corresponding near and far target grid points on the skin. Another strategy would entail the use of a "C" targeting device as previously described.

While the invention has been described by reference to certain preferred embodiments, it should be understood that numerous changes could be made within the spirit and scope of the inventive concept described. Accordingly, it is intended that the invention not be limited to the disclosed embodiments, but that it have the full scope permitted by the language of the following claims.

Claims

The invention claimed is:

1. A surgical targeting system **1** for adding an indicia image **2** to a radiographic image of a body **3** resulting from passage of image radiation through the body **4**, said targeting system **1** comprising:

   an antimicrobial drape **9** having an inner surface **11** of sufficient flexibility to conform to at least a portion of an outer surface **6** of the body **4**, said drape **9** being puncturable to provide access to the outer surface **6** of the body **4**, said drape **9** being transparent to the imaging radiation;

   an indicia **21** affixed to a portion of said drape **9**, said indicia **21** being opaque to the imaging radiation resulting in the indicia image **2** corresponding to said indicia **21**; and

   a means for fixing said indicia **21** relative to the outer surface **6** of the body **4** such that said indicia **21** provides a reference on the body **4** for correlating portions of the body **4** to the radiographic body image **3**.

2. The surgical targeting system 1 of claim 1 wherein said drape **9** comprises plastic impregnated with iodophor.

3. The surgical targeting system **1** of claim 1 wherein said indicia **21** comprises coordinates which are rectilinear and orthogonal.

4. The surgical targeting system **189** of claim 1 wherein said indicia **214** comprises polar coordinates.

5. The surgical targeting system **1** of claim 1 wherein said fixing means comprises adhesive **24** applied to said inner surface **11** of said drape **9**.

6. The surgical targeting system **1** of claim 5 wherein said adhesive **24** is applied continuously to the entire inner surface **11** of said drape **9**.

7. The surgical targeting system **156** of claim 1 wherein said drape **164** comprises a cylindrical portion **174**.

8. The surgical targeting system **156** of claim 7 wherein said drape **164** comprises an end portion **176** connected to and closing one end of said cylindrical portion **174**, said end portion being hemispherical.

9. The surgical targeting system **189** of claim 1 wherein said drape **196** is conical.

10. The surgical targeting system **189** of claim 9 wherein said indicia **214** comprises a system of polar coordinates having a center coinciding with an apex of said drape **196**.

11. A system **156** for providing a sterile field around an elongate body **159** comprising:

an antimicrobial drape **164** having a cylindrical portion **174** and an end portion **176** connected to and closing one end of said cylindrical portion **174**, said end portion **176** being hemispherical, said drape **164** having sufficient flexibility to conform to at least a portion of an outer surface **161** of the elongate body **159**, said drape **164** being puncturable to provide access to the outer surface **161** of the body **159**; and

means for fixing said drape **164** to the outer surface **161** of the body **159**, said drape **164** and fixing means being sterile to provide a sterile field around the outer surface of the body **159** accessed by puncturing of said drape **164**.

12. The sterile field system **156** of claim 11 wherein said drape **164** comprises plastic impregnated with iodophor.

13. The sterile field system **156** of claim 11 wherein said fixing means comprises adhesive **181** applied to the surface of said drape **164** which contacts the outer surface **161** of the body **159**.

14. The sterile field system **156** of claim 11 wherein said fixing means comprises forming said drape **164** of expandable material and sizing said drape **164** to have an internal volume which is less than the volume of the elongate body **159** enabling said drape **164** to be shrink-fitted onto the body **159**.

15. The sterile field system **156** of claim 11 wherein said drape **164** is transparent to imaging radiation,

said sterile field system **156** further comprising an indicia **179** affixed to a portion of said drape **164**, said indicia **179** being opaque to the imaging radiation such that a radiographic image of the body **183** resulting from passage of the image radiation through the body **159** includes an indicia image **182** corresponding to said indicia **179**,

said fixing means fixing said indicia **179** relative to the outer surface **161** such that said indicia **179** provides a reference on said body **159** for correlating portions of the body **159** to the radiographic image thereof **183**.

16. A system **189** for providing a sterile field around a conical body **191** comprising:

a conical antimicrobial drape **196** having sufficient flexibility to conform to at least a portion of an outer surface **194** of the conical body

191, said drape **196** being puncturable to provide access to the outer surface **194** of the body **191**; and

means for fixing said drape **196** to the outer surface **194** of the body **191**, said drape **196** and fixing means being sterile to provide a sterile field around the outer surface **194** of the body **191** accessed by puncturing of said drape **196**.

17. The sterile field system **189** of claim 16 wherein said drape **196** comprises plastic impregnated with iodophor.

18. The sterile field system **189** of claim 16 wherein said fixing means comprises adhesive **216** applied to the surface **201** of said drape **196** which contacts the outer surface **194** of the body **191**.

19. The sterile field system **189** of claim 16 wherein said drape **196** has a radial cutout **206** having a base **209** which coincides with a peripheral edge **204** of said drape **196**.

20. The sterile field system **189** of claim 16 wherein said drape **196** is transparent to imaging radiation,

said sterile field system **189** further comprising an indicia **214** affixed to a portion of said drape **196**, said indicia **214** being opaque to the imaging radiation such that a radiographic image of the body **223** resulting from passage of the image radiation through the body **191** includes an indicia image **222** corresponding to said indicia **214**,

said fixing means fixing said indicia **214** relative to the outer surface **194** such that said indicia **214** provides a reference on said body **191** for correlating portions of the body **191** to the radiographic image thereof **223**.

said drape **196**.

22. A method for correlating a selected portion of a body **4** to a radiographic image of the body **3** for treatment of the body **4**, said method comprising the steps of:

applying a radio-transparent drape **9** having radio-opaque indicia **21** to the body **4**;

fixing said drape **9** and indicia **21** to the body **4**;

directing imaging radiation through said drape **9** and indicia **21** such that a radiographic image of said body **3** and indicia **2** is formed on a medium;

referencing on the radiographic image the selected portion of the body **3** relative to the indicia **2**;

locating the selected portion of the body **4** by referencing the body **4** relative to the indicia **21** on the drape **9** in a manner corresponding to said referencing of the radiographic image; and

puncturing the drape **9** to access the body **4** for treatment thereof.

23. The method of claim 22 and further comprising the steps of:

referencing a second selected portion of the body **3** on the radiographic image relative to the indicia **2** on the radiographic image; and

locating the second selected portion of the body **4** by referencing the body **4** relative to the indicia **21** on the drape **9** in a manner corresponding to said referencing of the second selected portion of the radiographic image.

24. The method of claim 22 wherein said applying step comprises placing the drape **9** on the body **4** such that the body **4** is disposed between at least two portions of the indicia **21**, said placing of the drape **9** further providing that each said portion of the indicia **21** is contained in a separate plane which is in parallel separation to the other plane.

25. The method of claim 22

wherein said applying step comprises placing the drape **9** on the body **4** such that the body **4** is disposed between at least two portions of the indicia **21**,

wherein said referencing step comprises identifying on the radiographic image the portions of the indicia **2** intersected by an axis coinciding with a selected direction through the body **4**,

wherein said locating step comprises locating the selected direction through the body **4** by referencing the body **4** relative to the portions of the indicia **21** on the drape **9** identified in said referencing of the radiographic image;

wherein said puncturing step comprises puncturing the drape **9** to access the body **4** adjacent to at least one of the portions of the indicia **21**.

26. A method for correlating a selected portion of a body **4** to a radiographic image of the body **3** for treatment of the body **4**, said method comprising the steps of:

applying a radio-transparent drape **9** having radio-opaque indicia **21** to the body **4**;

fixing said drape **9** and indicia **21** to the body **4**;

directing imaging radiation through said drape **9** such that a radiographic image of said body **3** and indicia **2** is formed on a medium;

referencing on the radiographic image the selected portion of the body **3** relative to the indicia **2**;

locating the selected portion of the body **4** by referencing the body **4** relative to the indicia **21** on the drape **9** in a manner corresponding to said referencing of the radiographic image; and

surgically operating on the body **4** contemporaneously with said locating step.

27. A method for correlating a selected portion of a body **4** to a radiographic image of the body **3** for treatment of the body **4**, said method comprising the steps of:

applying a radio-transparent drape **9** having radio-opaque indicia **21** to the body **4** such that portions of the drape **9** define at least two surfaces inclined relative to one another;

fixing said drape **9** and indicia **21** to the body **4**;

directing imaging radiation through said drape **9** such that a radiographic image of said body **3** and indicia **2** is formed on a medium;

referencing on the radiographic image the selected portion of the body **3** relative to the indicia **2**, said referencing step further comprising identifying on the radiographic image respective indicia **2** on the inclined two surfaces, said respective indicia **2** being intersected by an axis coinciding with a selected direction through the body **4**, said referencing step further comprising identifying on the radiographic image indicia **2** on one of the inclined two surfaces coinciding with the depth of the selected direction relative to the other of the inclined two surfaces; and

locating the selected portion of the body **4** by referencing the body **4** relative to the indicia **21** on the drape **9** in a manner corresponding to said referencing step of the radiographic image, said locating step comprising identifying the selected direction and depth through the body

4 by referencing the body **4** relative to the indicia **21** on the drape **9** identified in said referencing step of the radiographic image.

28. A method for correlating the buttock **76** with the femoral canal of the femur of a body **126**, said method comprising the steps of:

applying a radio-transparent drape **81, 131** having at least two indicia **99, 144** each comprising a radio-opaque longitudinal axis to the leg of the body **126** such that a first portion of the drape **81, 131** extends in an anterior-posterior plane relative to the body **76, 126**, said applying step further providing for a second portion of the drape **81, 131** to extend laterally relative to the body **76, 126**, said applying step providing further for each of the indicia **99, 144**, to be contained in respective first and second portions of the drape **81, 131**, said applying step providing further for each of the indicia **99, 144**, to be longitudinally and centrally aligned relative to the leg **126**;

directing imaging radiation through said drape **81, 131**, such that a radiographic image of said body **109, 111, 114, 116, 119, 121, 148, 149**, and indicia **108, 147** is formed on a medium;

comparing, by viewing the radiographic image, the relative positions of each of the indicia **108, 147** relative to the longitudinal axis of the femoral canal;

translating the drape **81, 131**, as required, relative to the leg **126** such that one of the indicias **99, 144** is contained in an anterior-posterior plane which coincides with the longitudinal axis of the femoral canal, and such that the other of the indicia **99, 144** is contained in a lateral plane which coincides with the longitudinal axis of the femoral canal; and

locating the intersection of the indicia **99** on the buttock **76**, the intersection of the indicia **99** defining a start point for a reference axis which, when intersecting said start point and parallel to the indicia **99**,

coincides with the longitudinal axis of the femoral canal.

29. A method as set forth in claim 28 and further comprising the steps of:

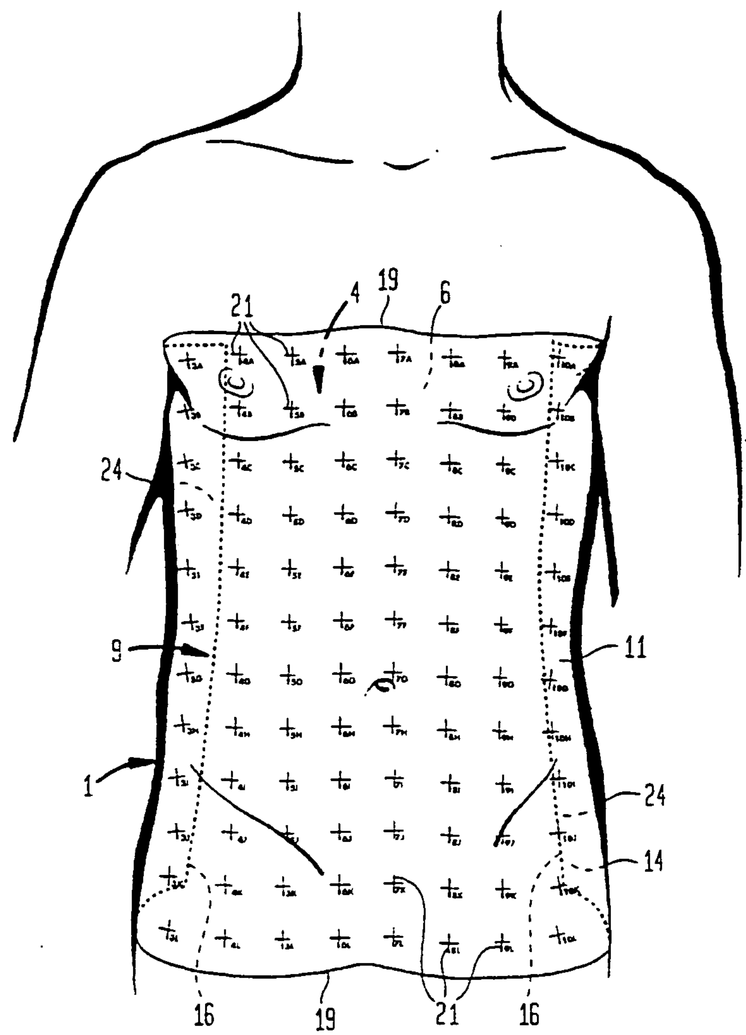
positioning a longitudinal nail relative to the leg **126** such that a pointed end of the nail is adjacent to the start point on the buttock **76**;

orienting the nail relative to the leg **126** such that the longitudinal axis of the nail coincides with the reference axis;

inserting the nail through the tissue of the leg **126** such that the longitudinal axis of the nail coincides with the reference axis, said inserting step being initiated by puncturing the outer surface of the leg **126** at the start point with the pointed end of the nail;

inserting the nail further through the tissue **126** such that the longitudinal axis of the nail continues to coincide with the reference axis, and such that the pointed end of the nail punctures the proximal end of the femoral canal; and

inserting the nail further into the femoral canal such that the longitudinal axis of the nail continues to coincide with the reference axis.



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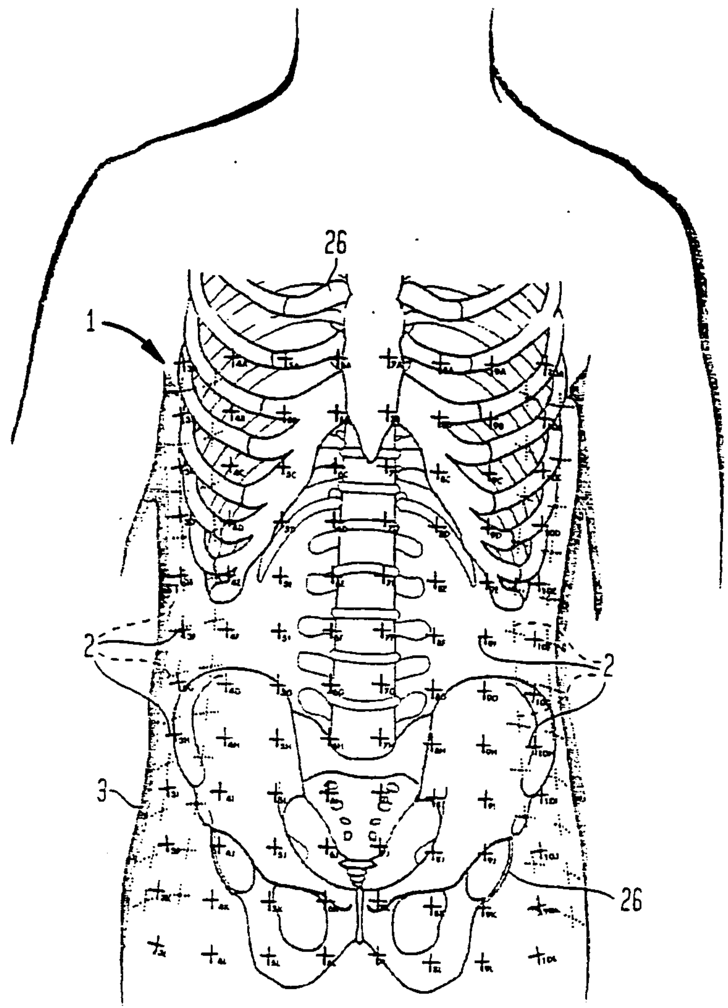

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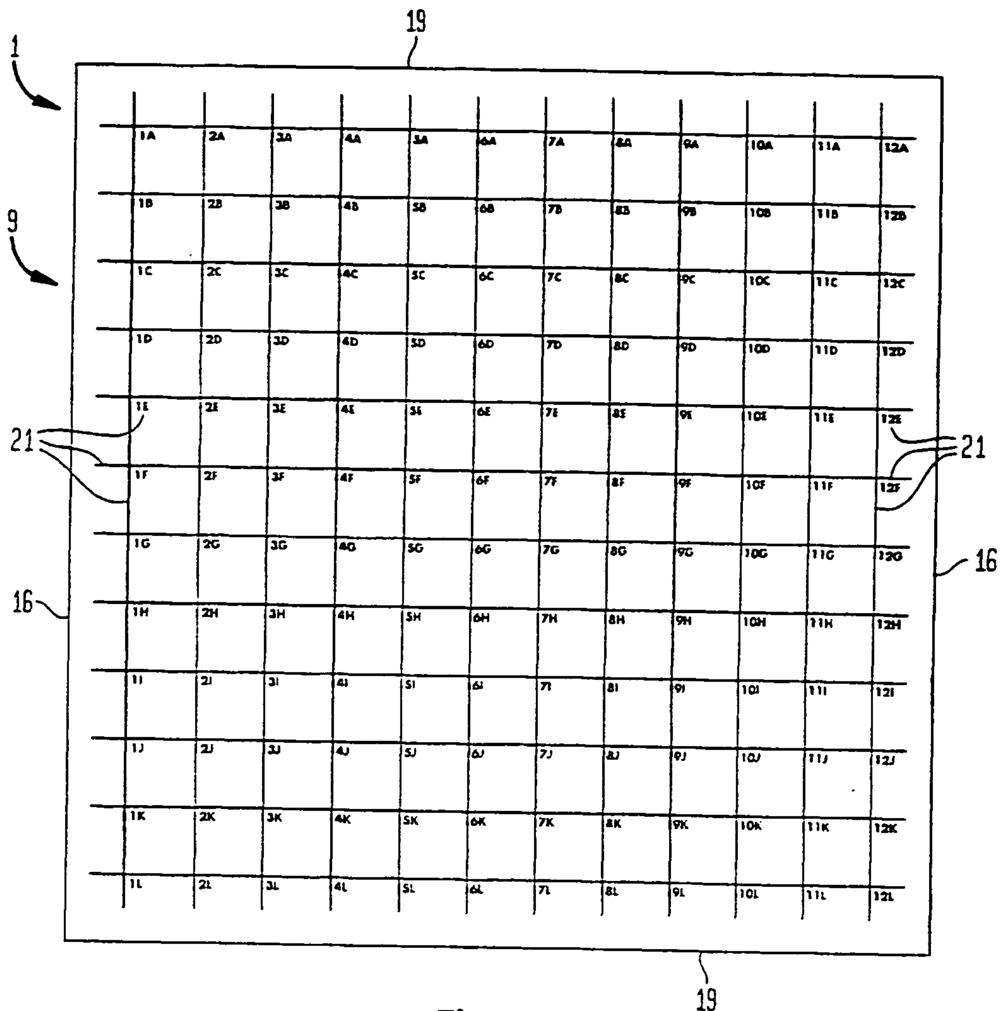
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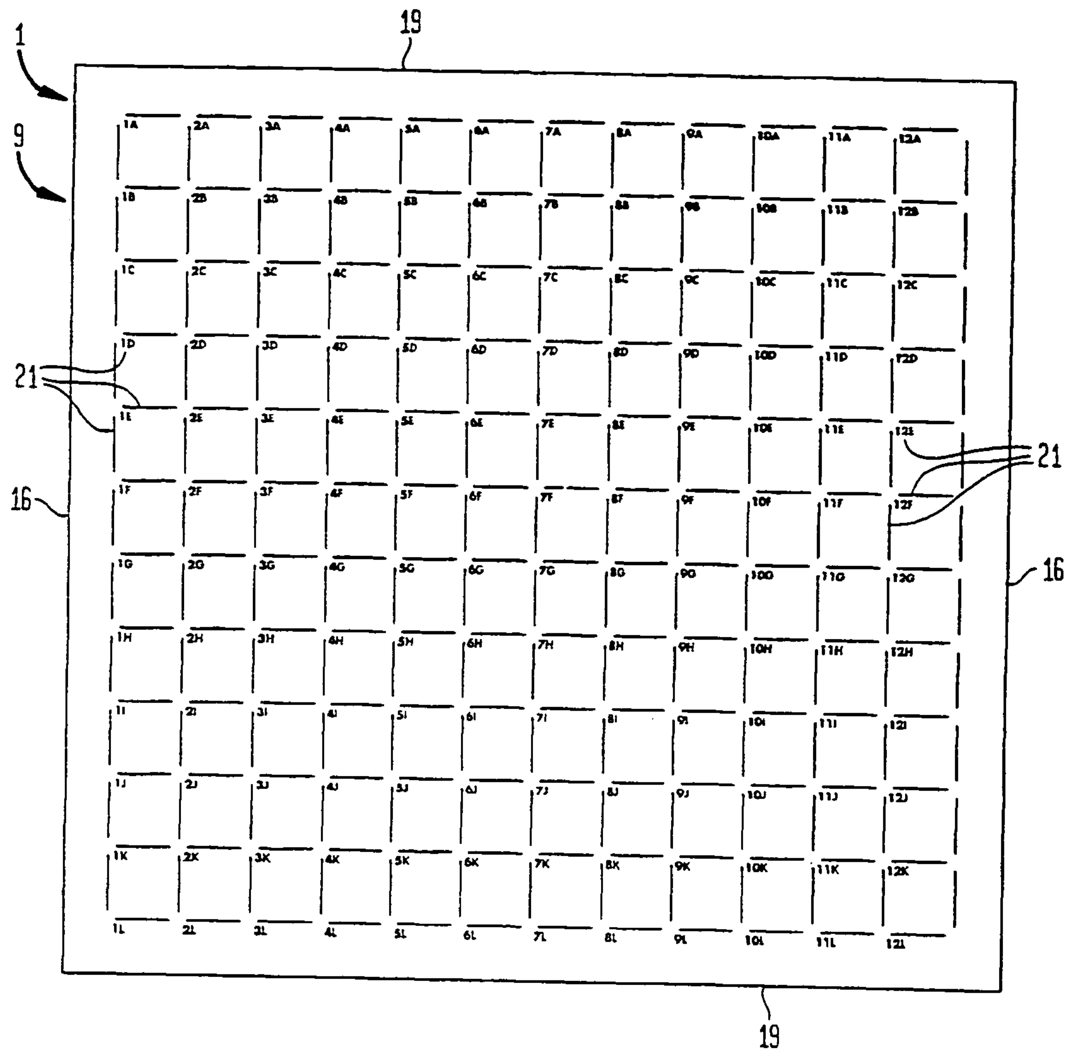
Figure 3



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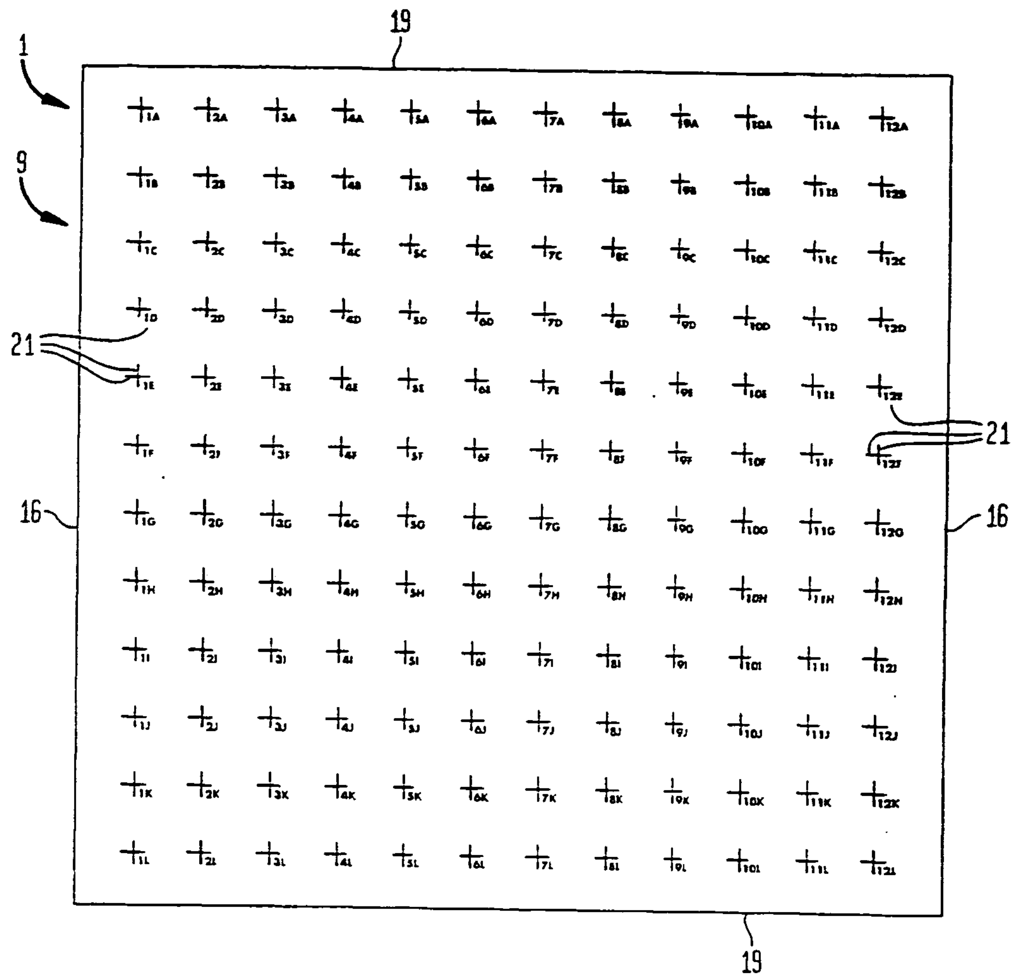

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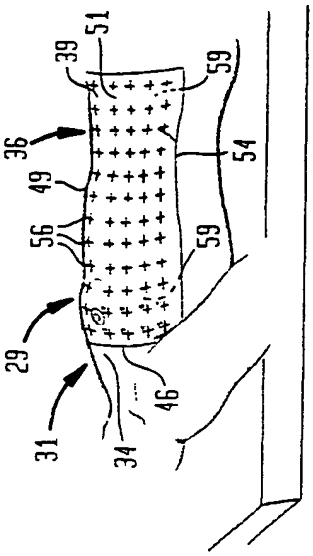

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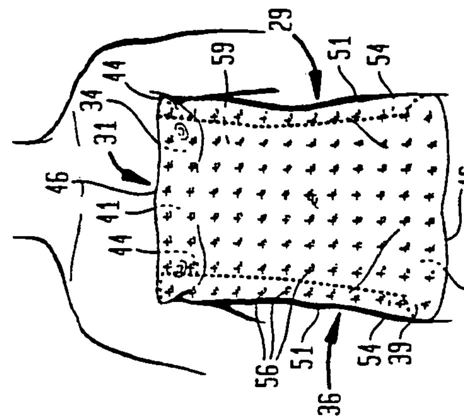

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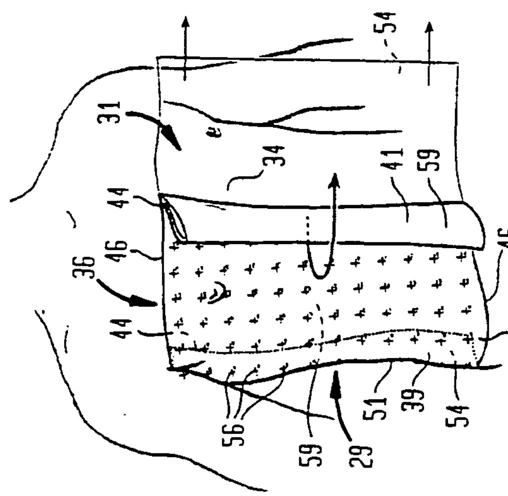

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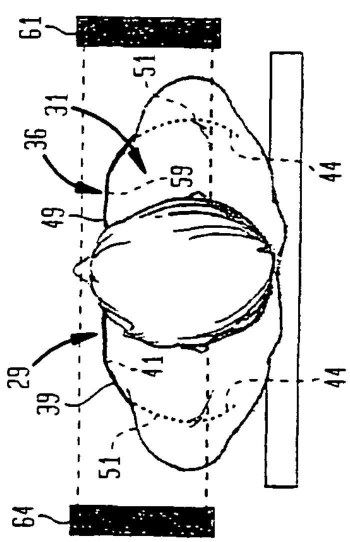

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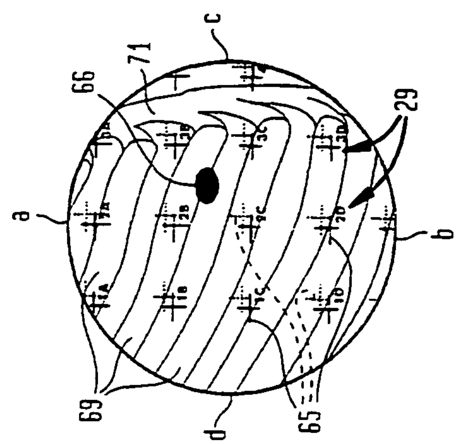

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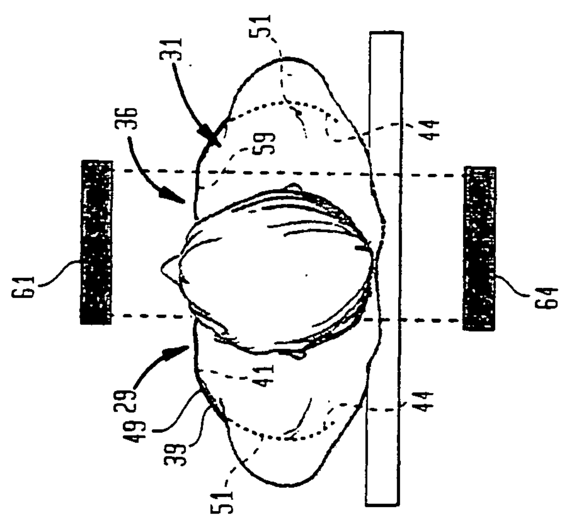

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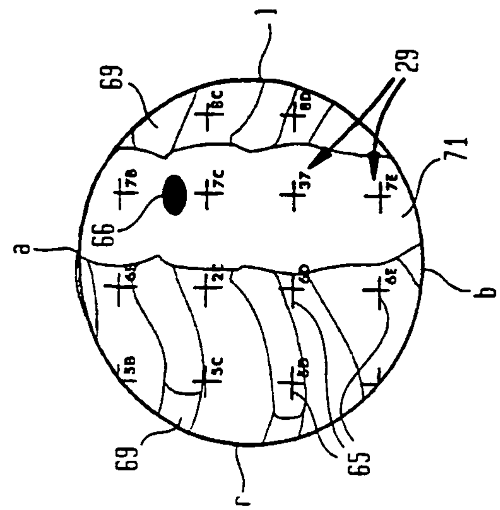

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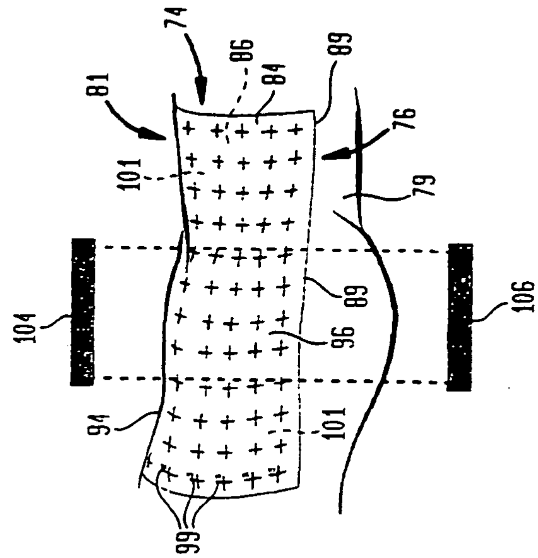

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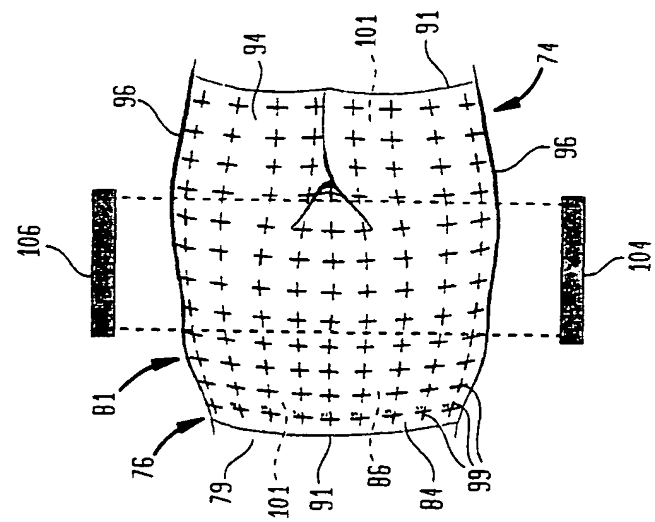

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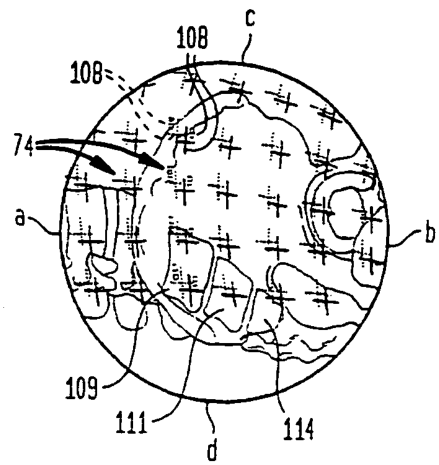

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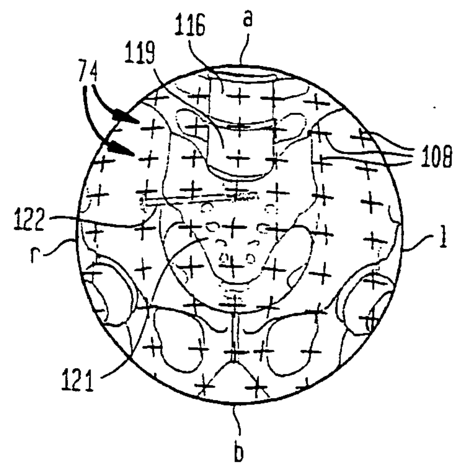

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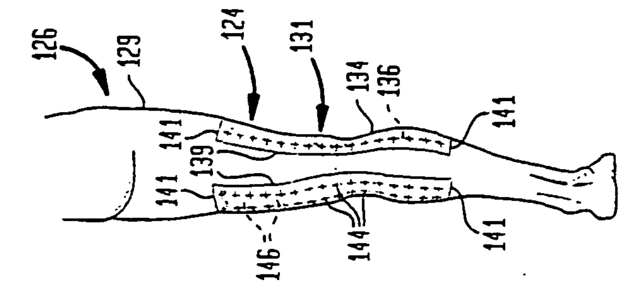

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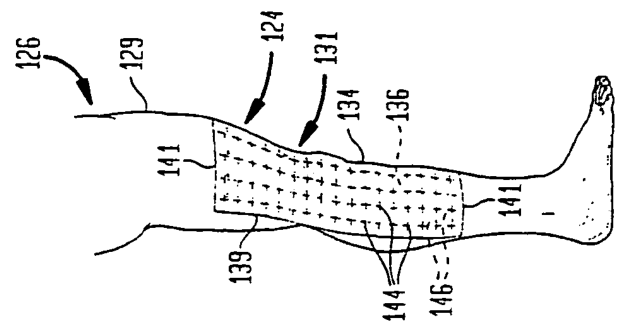

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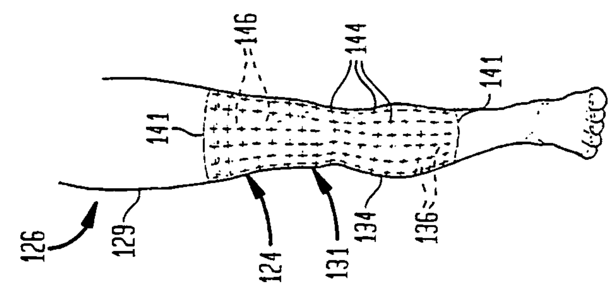

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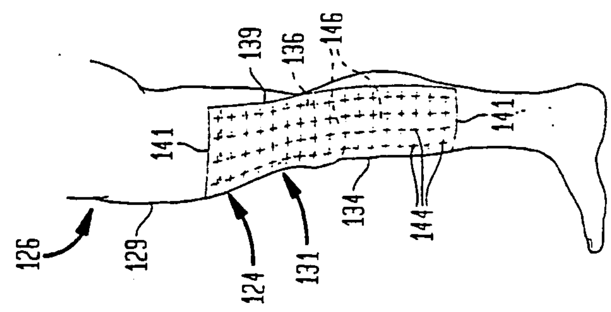

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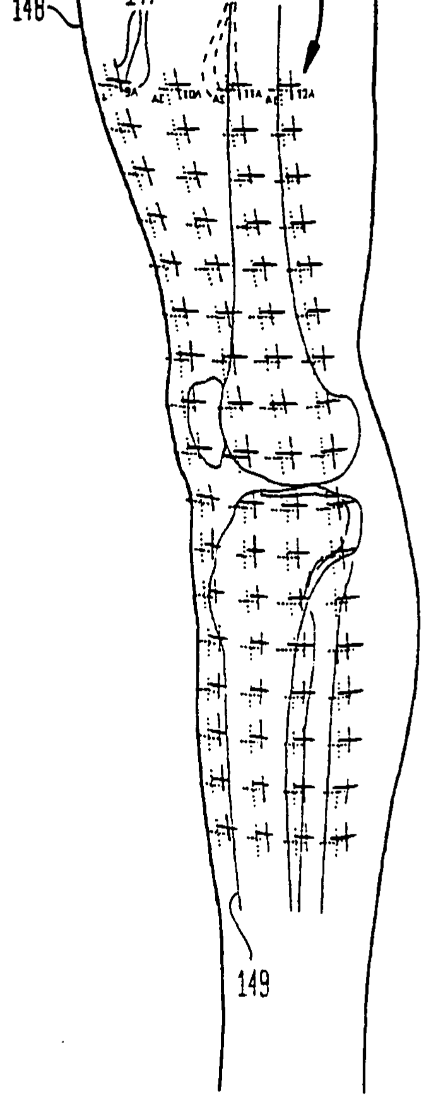

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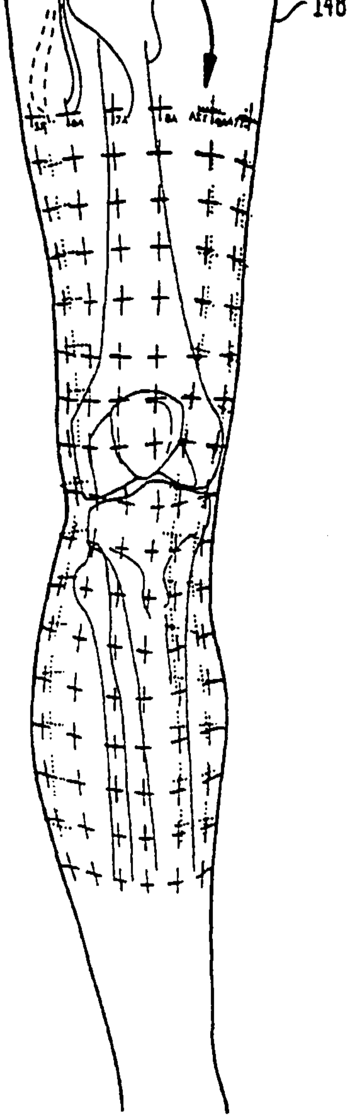

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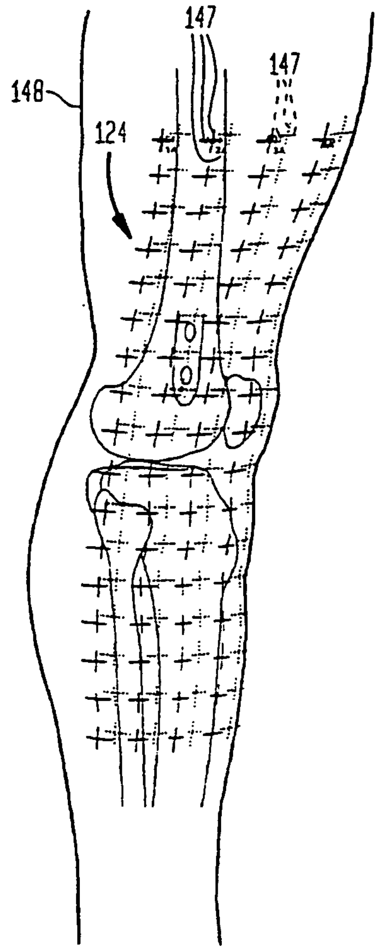

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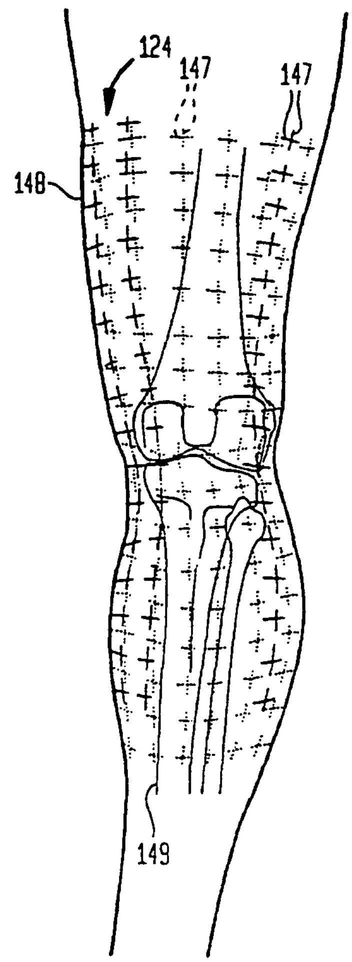

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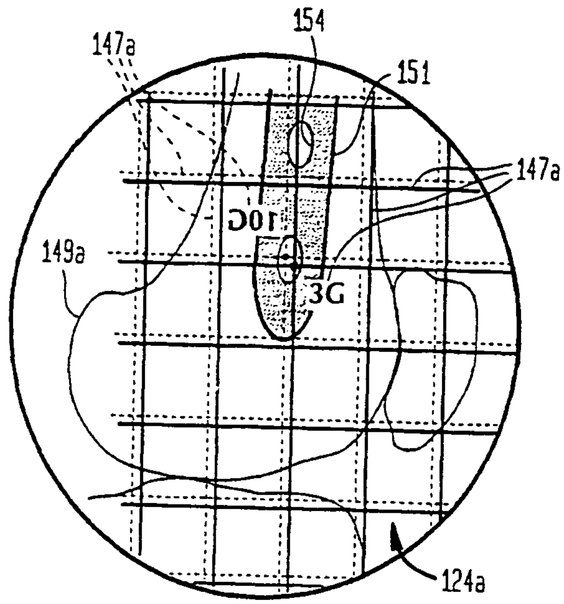

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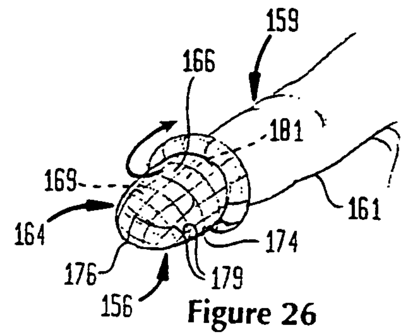

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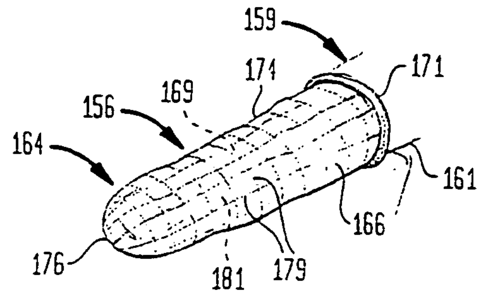

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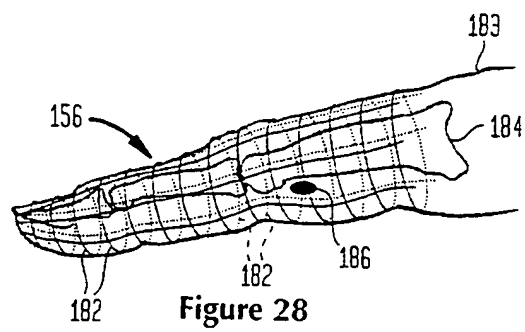

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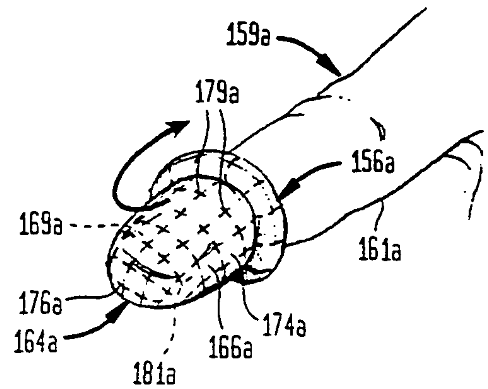

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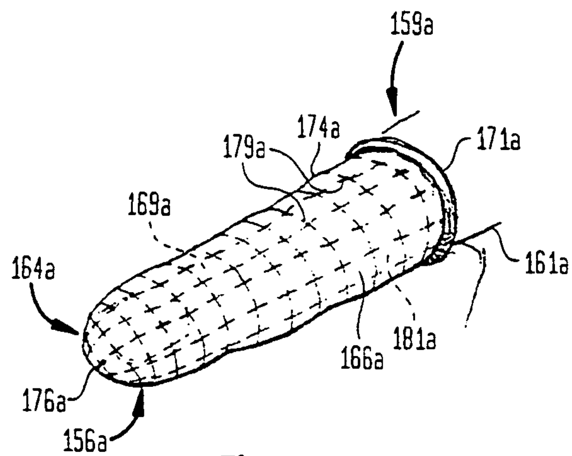

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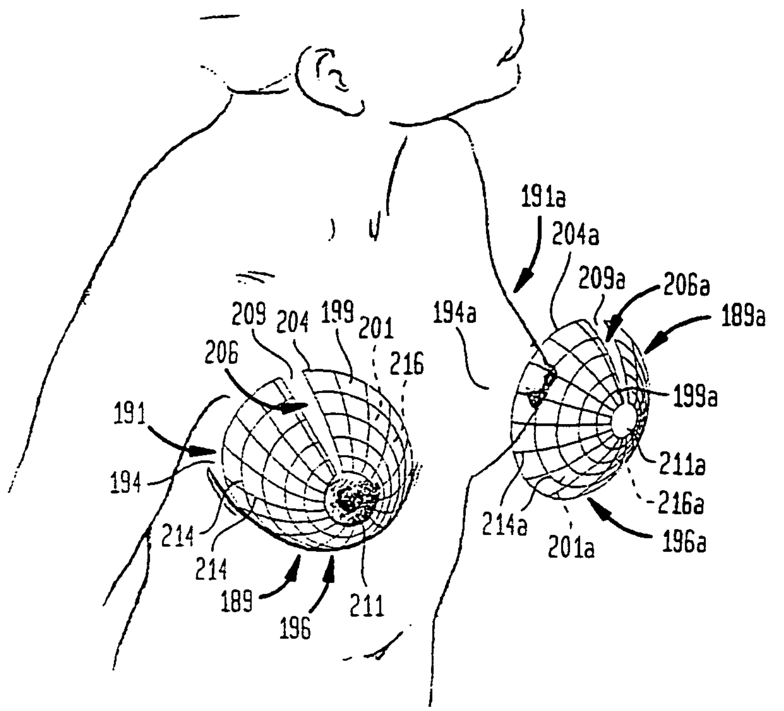
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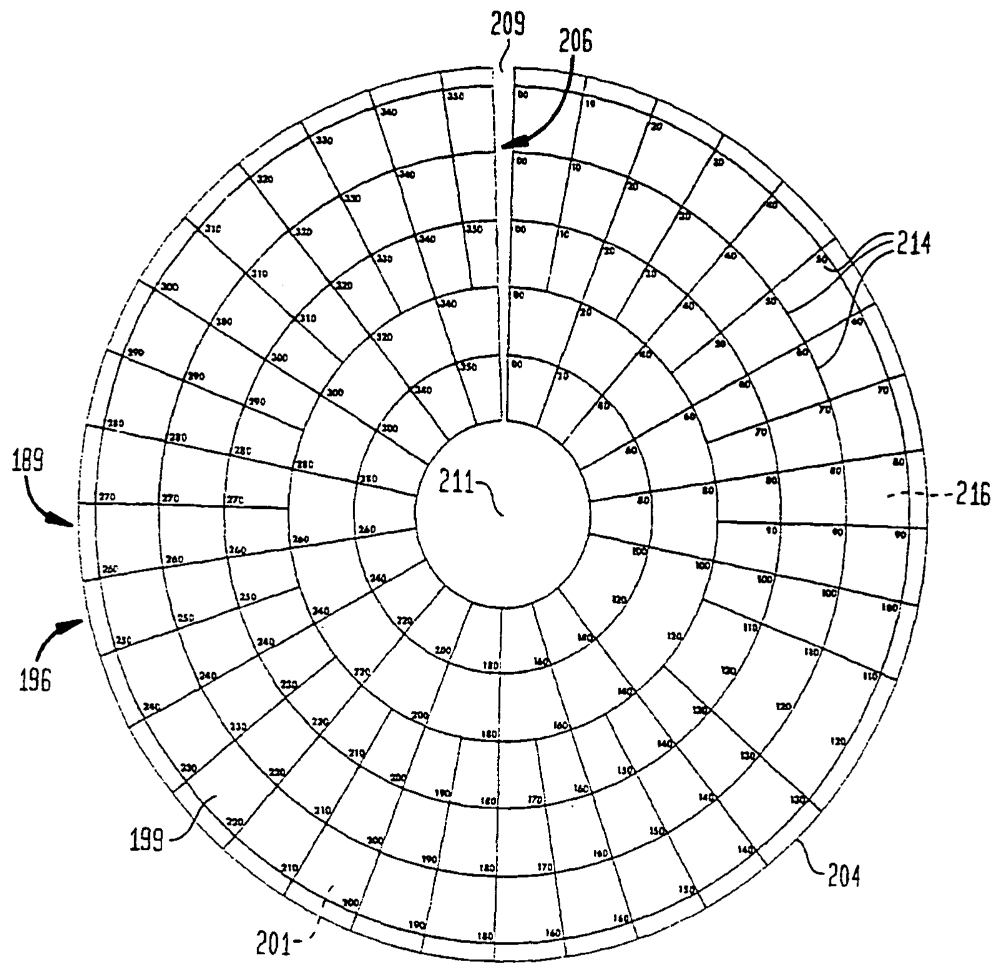
Figure 31



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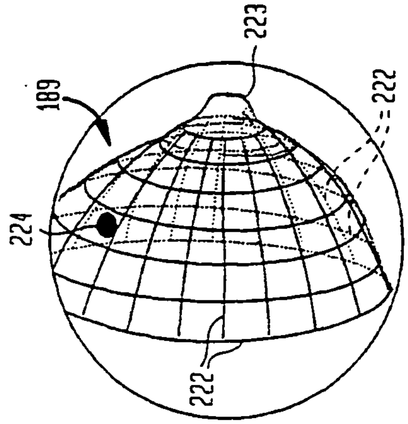

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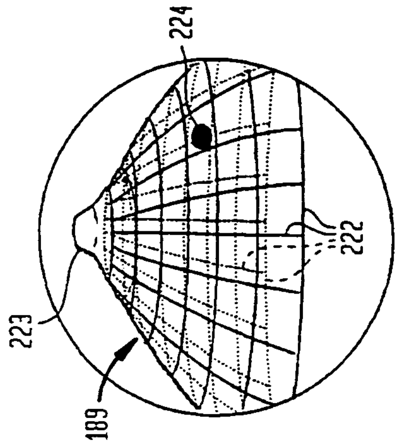

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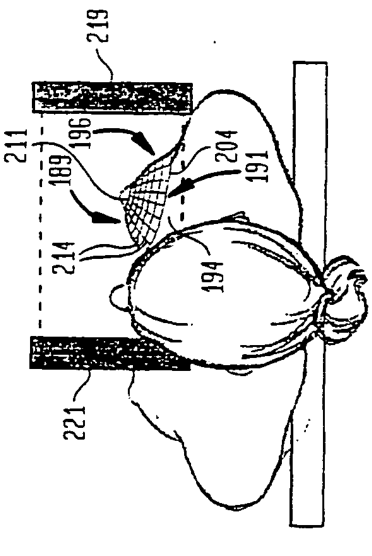

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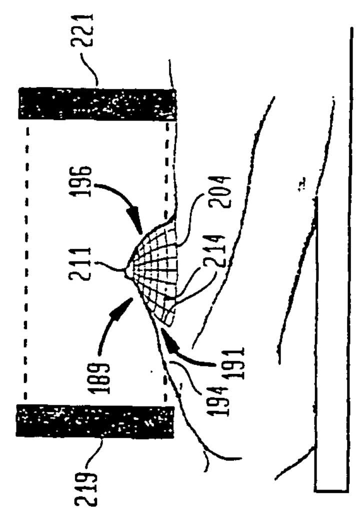

Figure 35

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 6/00

US CL :600/426

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/425, 426, 429, 407; 378/164, 20, 205, 163; 128/849, 852, 853; 606/130

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,938,233 A (ORRISON Jr.) 03 July 1990, see entire document.	1
Y	US 5,242,985 A (SHIH et al.) 07 September 1993, see entire document.	2, 5-6
Y	US 5,260,985 A (MOSBY) 09 November 1993, see entire document.	4, 7-27
Y	US 4,838,265 A (COSMAN et al) 13 June 1989, see entire document.	3, 28-29

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
01 JULY 2001	26 SEP 2001

Name and mailing address of the ISA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	ELENI MANTIS MERCADER
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